Expanding Access to Movement Disorders Care and Research

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Rochester, New York
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Disclosures

- Presbyterian Home of Central New York
- Susquehanna Nursing and Rehabilitation Center
- Samaritan Keep Nursing Home
- Otsego Focus Nursing and Rehabilitation Center
- Sitrin Nursing Home
- Greater Rochester Health Foundation
- AMC Health
- NINDS

Outline

- Access to neurological care is vital but limited
- Telemedicine facilitates access to care
- Technology can improve clinical research

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- Telemedicine facilitates access to care
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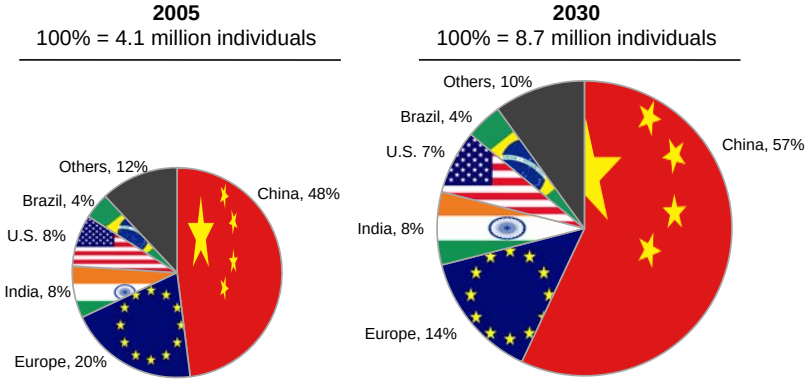
The burden of chronic conditions such as Parkinson disease is growing globally

Distribution of individuals with Parkinson disease by country from 2005 to 2030*



*Among individuals over 50 in the world's ten most and Western Europe's five most populous nations

Source: Neurology 2007;68:384-6

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Increased access to specialists can improve care and outcomes

Model of improving outcomes

Specialists lead to higher quality care
- **Heart disease** → More appropriate medication use
- **Asthma** → Greater adherence to national management guidelines
- **Diabetes** → Better process measures

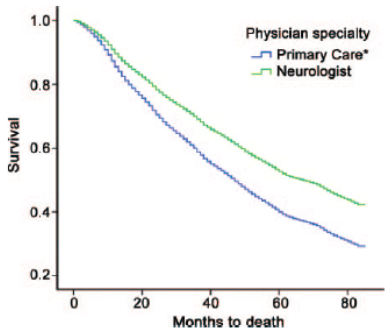
Higher quality care improves outcomes
- **Heart failure** → Increased survival
- **Asthma** → Improved quality of life
- **Diabetes** → Fewer complications

In Parkinson disease, movement disorder specialist involvement is associated with higher adherence to quality indicators than general neurologist or other specialty involvement

Sources: NEJM 1994;331:1136-42; Arch Int Med 1998;158:457-64; Diabetes Care 2004;27:398-406; CMAJ 2005;172:189-94; J Allergy Clin Immunol 2005;116:1307-13; Mov Disord 2007;22:515-22

Access to Neurologist Care is Vital

Figure Survival of Medicare beneficiaries with incident Parkinson disease stratified by treating physician specialty, adjusted for race, age, sex, comorbidity index, and socioeconomic deprivation



*Physicians in the following specialties: internal medicine, family practice, or geriatric medicine.

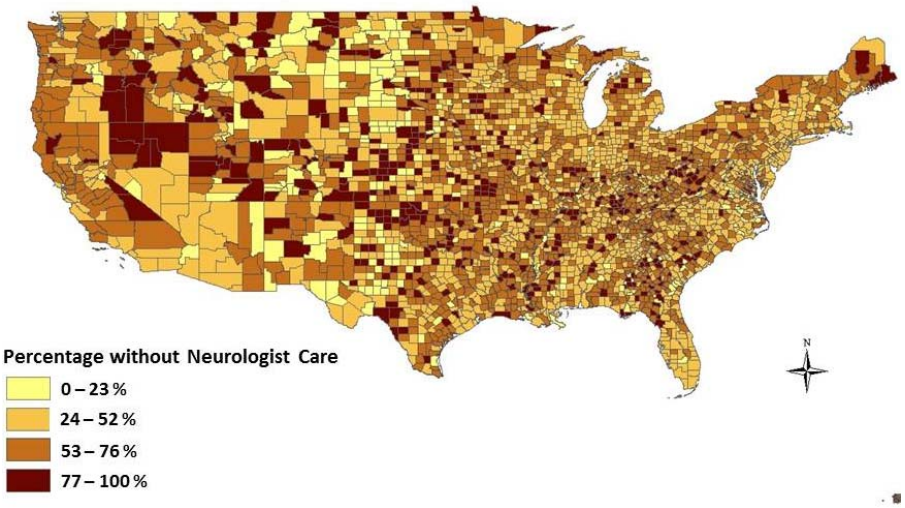
Neurologist Care in PD

- 14% reduction in hip fracture
- 21% reduction in SNF
- 22% less likely to die

A.W. Willis et al. Neurology 2011;77:851-857

However, access to neurological care is limited in the United States

Proportion of Medicare beneficiaries with PD who do not see a neurologist



Source: Dorsey ER, George BP, Leff B, Willis AW. The coming crisis: obtaining care for the growing burden of neurodegenerative conditions. Neurology 2013; 80:1989-96

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Outline

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- **Telemedicine facilitates access to care**
- Technology can improve clinical research
- Vision for movement disorders in South Florida

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Simple, inexpensive technology can reach patients with PD wherever they live

Novel application of existing technology

Equipment
- Internet-enabled device
- Web cam, microphone
- Encrypted software

- In-home care
- Remote patient monitoring
- Remote study participation

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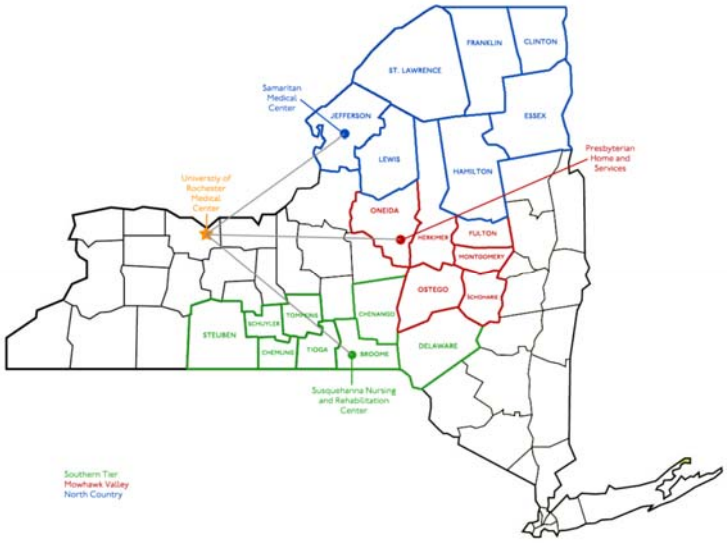
University of Rochester Telemedicine Network of Upstate New York

A spoke and hub model providing care to communities through regional nursing homes



We conducted a pilot, randomized controlled study to evaluate the feasibility of a spoke and hub model

Pilot randomized, controlled study of telemedicine for Parkinson disease

4 nursing home residents with PD → 3 telemedicine visits over 6 months

10 individuals from the local community with PD → "Usual care" for 6 months

10 individuals from the local community with PD → 3 telemedicine visits over 6 months

Outcomes

Primary outcome
- Feasibility as measured by proportion of telemedicine visits completed as scheduled

Secondary outcomes
- Reliability and validity of the UPDRS motor examination
- Quality of life
- Patient satisfaction
- Motor performance
- Mood
- Cognition

Telemedicine visits were feasible
Remote assessment of the UPDRS was reliable
QOL, satisfaction with care and motor function improved

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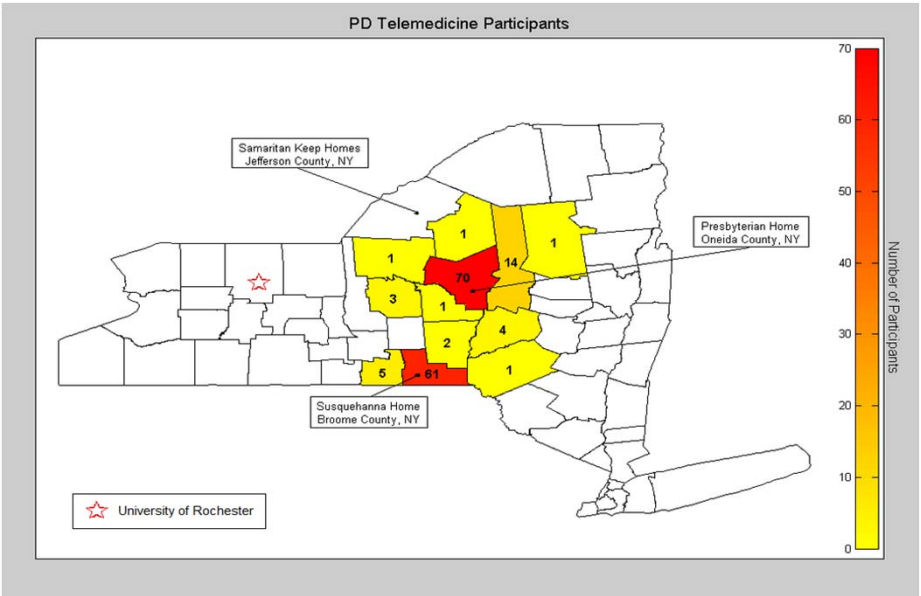
Source: Pilot randomized controlled trial of telemedicine for individuals with Parkinson disease. International Congress of Parkinson's Disease and Movement Disorders. June 7-11, 2009.

This model increases access to individuals residing in rural communities



More importantly, patients were touched …

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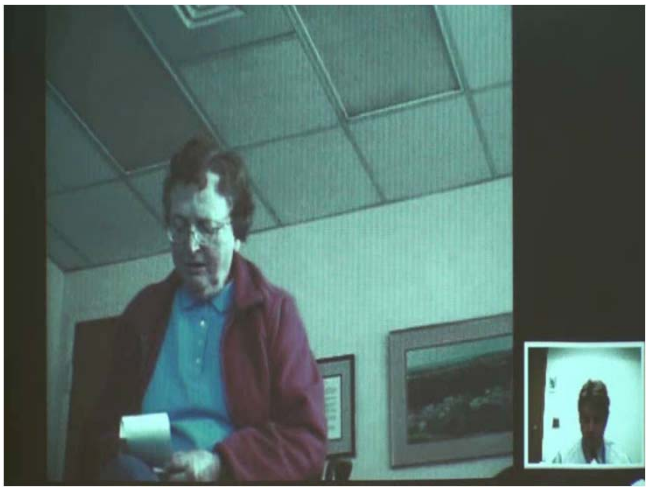
… and moved by the experience



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The same model can be extended into the home…

“Virtual House calls”

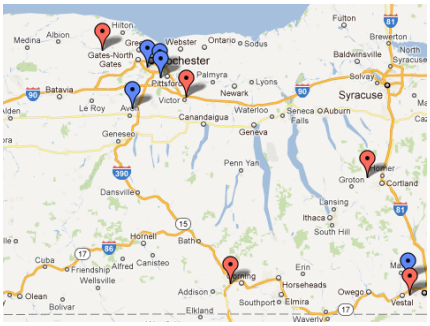
A randomized controlled trial of virtual house calls for PD

20 patients with PD at two centers

- 11 patients receive 3 in-person visits over 6 months
- 9 patients receive 3 telemedicine visits over 6 months in home

Outcomes

1. Feasibility
2. Clinical outcomes
3. Economic value



Telemedicine In-person

Average distance from UR Movement disorders Clinic

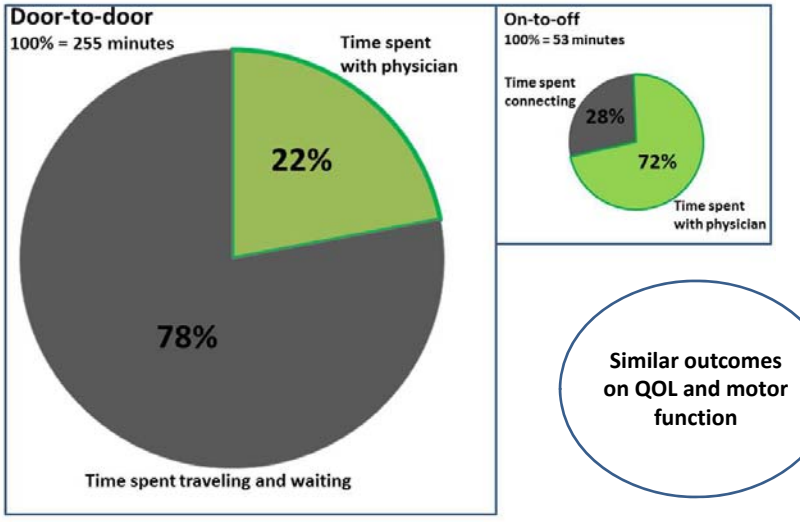
55.8 miles and average drive time of 64.7 minutes

Sponsors:

Google Excellus

Virtual house calls flip the care paradigm

Patient time spent on in-person versus telemedicine visits



Similar outcomes on QOL and motor function

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Source: JAMA Neurology 2013;70:565-70.

We have completed a national randomized controlled trial of telemedicine for Parkinson disease

In collaboration with: National Parkinson Foundation; pcori; SBR Health Deliver Care Anywhere; patientslikeme; Vidyo

Source: Telemedicine and e-Health. February 2016 (ePub ahead of print)

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Connect.Parkinson

connecting anyone anywhere to care

PRELIMINARY RESULTS

Feasibility

98% of individuals completed at least one telemedicine visit

91% of 388 telemedicine visits completed as scheduled

Value

Median of 80 minutes and 108 miles per visit saved in telemedicine group. Despite this there was no difference in caregiver strain

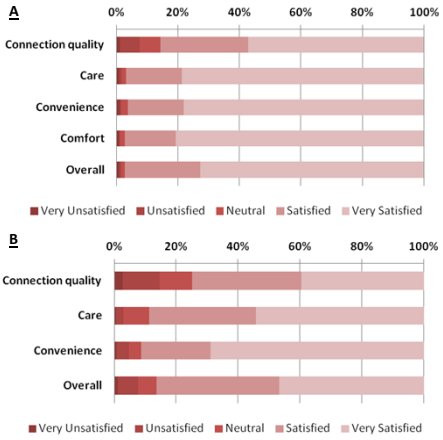
Effectiveness

No difference in PDQ39 (QOL, 0-100); 95% CI -2.0-2.7, p=0.78

Both groups improved in PACIC (quality of care, 0-5) but no difference between groups; 95% CI -0.21-0.28, p=0.79

Patients and Physicians were satisfied with the telemedicine visits

Figure 1. Patient (1A) and Parkinson disease specialist (1B) satisfaction with aspects of virtual visits



Selected patient feedback

- "I learned more in one visit than all the information provided by other physicians over a period of years!!!"
- "I felt it was a great doctor's visit. Better than many I've had face to face."
- "It was so good to not have to ride 45 minutes in a handicapped van each way to see a (movement disorder specialist)."

Selected physician feedback

- "Visit interaction was great, but it was very difficult to determine actual ratings for rapidly alternating movements."
- "Video quality, particularly for rating Unified Parkinson's Disease Rating Scale is frustrating."
- "I think it is fine for the interview part, and maybe for clinical follow-ups."

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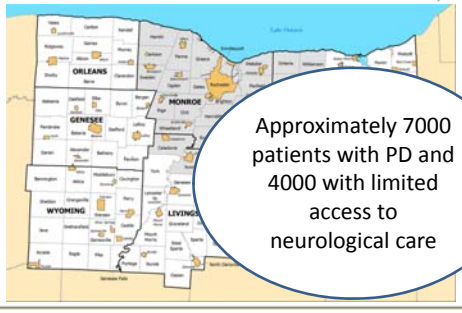
Source: Telemedicine and e-Health. February 2016 (ePub ahead of print)

We are launching PDCNY to enable any New Yorker with PD to receive multidisciplinary care in the home

PDCNY

Parkinson's Disease Care, NEW YORK



Approximately 7000 patients with PD and 4000 with limited access to neurological care

Supported by:

greater rochester Health foundation

EDMOND J. SAFRA PHILANTHROPIC FOUNDATION

NATIONAL PARKINSON FOUNDATION

UNIVERSITY of ROCHESTER

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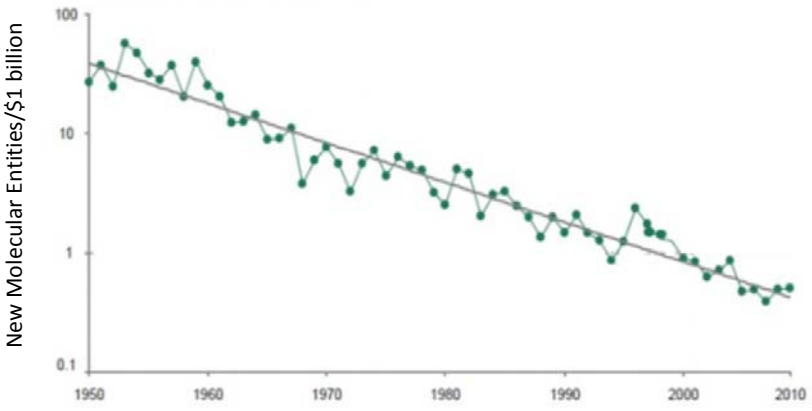
The productivity of the drug development industry continues to decline

New molecular entities per $1 billion in R&D (inflation adjusted), 1950-2010



Source: http://www.forbes.com/sites/matthewherper/2011/06/27/the-decline-of-pharmaceutical-researchmeasured-in-new-drugs-and-dollars/

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To help stem the productivity decline, change is needed

Characteristics of 20th vs 21st century clinical trials

Characteristic	20th Century	21st Century
Study design	Randomized, double-blind, parallel-group, placebo-controlled trial	Randomized, double-blind, parallel-group, placebo-controlled trial using adaptive designs
Study population	All comers with a given disease	Individuals selected based on phenotypic and genetic results
Study recruitment	Clinical practices	Global clinical trial registries and social networks organized by individuals affected by the disease
Trial visits	In person and audio calls	In person and audio and video calls
Data management	Paper and electronic forms	Electronic forms
Participant feedback	Limited, delayed	Almost universal, approximately real time
Outcome measures	Insensitive	Sensitive
	Episodic	Frequent or continuous
	Subjective	Objective
	Provider centered	Patient centered
	In clinic	Remote
	Unidimensional	Multidimensional

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Source: JAMA Neurol. 2015 May;72(5):582-8.

Virtual research visits can improve efficiency of clinical trials

Facilitate recruitment

- Recruitment most common and costly cause for trial delays
- Remote recruitment may reduce geographic barriers
- May improve access to underserved populations with unmet therapeutic needs (e.g., nursing home patients)

Maximize retention

- Disease modifying trials in neurodegenerative disease require long duration follow up
- Frequent in-person assessment impacts retention
- Virtual visits may reduce burden to ongoing participation

Reduce variability in assessment

- Centralized remote raters
- Reduce variability
- Greater power and smaller sample size

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A modified UPDRS conducted remotely is cross-sectionally and longitudinally valid

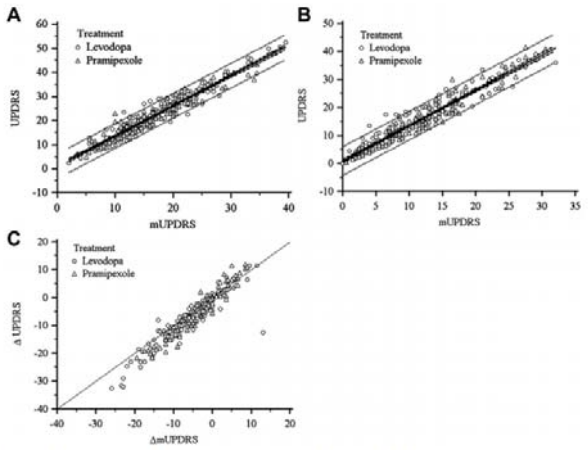

Fig. 1. Scatter plots for (A) modified motor UPDRS (mUPDRS) versus standard motor UPDRS at baseline, (B) mUPDRS versus UPDRS at 2-year follow-up, and (C) change from baseline to 2-year follow-up for mUPDRS versus UPDRS. Solid lines represent best-fit linear regression line (plots A and B) and line of identity (plot C). For plots A and B, dashed line represents 95% confidence interval and dotted line represents 95% prediction interval about the best-fit line.

Feasibility and Value of Virtual Research Visits Using Fox Trial Finder

Methods

•Fox Trial Finder participants provided consent by phone, completed baseline surveys, downloaded video conferencing software, and received a web camera.

•After a test connection, participants underwent a remotely assessed cognition and had a virtual research visit to:

(1) Review their history
(2) Perform MDS-UPDRS (modified to exclude assessments of rigidity and balance)
(3) Confirm whether PD was the most likely diagnosis
(4) Solicit feedback on their experience

Results

•81.4% individuals from 39 states completed the visits

•On average, participants were:
(1) 61.6 years old
(2) Had Parkinson disease for 8.0 years
(3) Scored 26.5 on the Montreal Cognitive Assessment
(4) Had modified motor score of 22.8.
(5) Parkinson disease was most likely diagnosis in 97.0% of cases.

•Overall satisfaction with the visits was 79% (satisfied or very satisfied) among neurologists and 93% among participants.

Source: Journal of Parkinson's Disease, 2015; 5: 505-515

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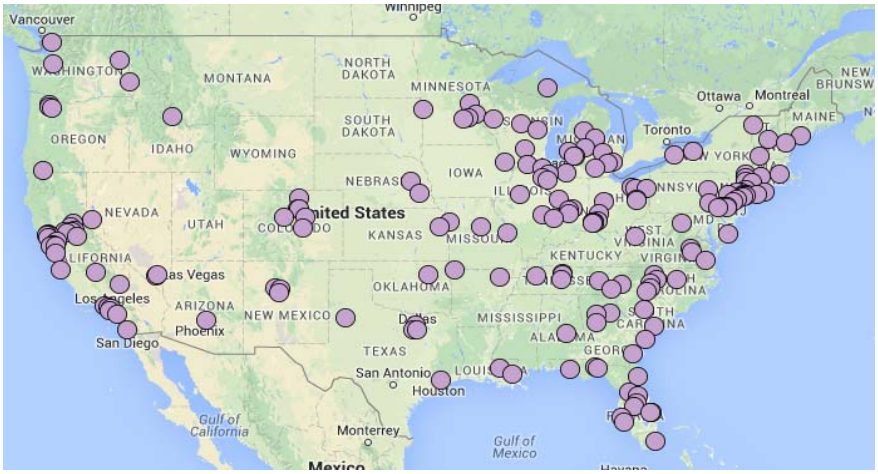
In this study we connected remotely to over 160 participants in 39 states

Map of participants



Source: Journal of Parkinson's Disease, 2015; 5: 505-515

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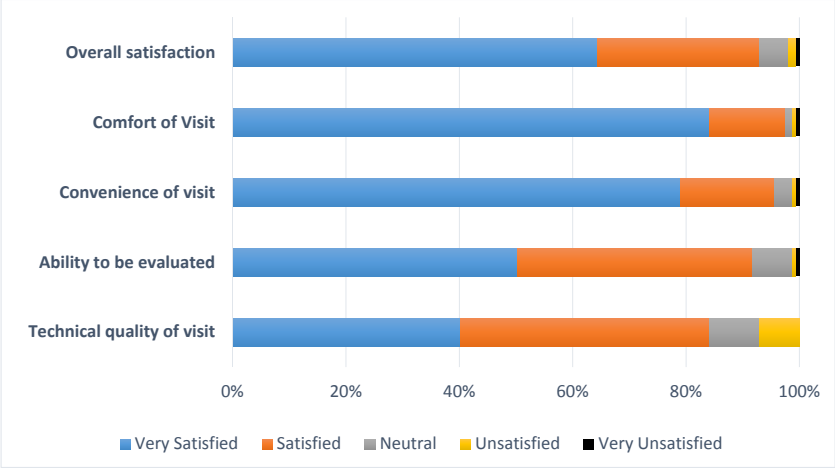
Research participants were satisfied with the virtual visits



Over 80% of participants said they would be more willing and able to participate in future research studies if could do so remotely

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Entire clinical trials can be conducted remotely

Characteristics of select web-based clinical trials

Source	Design	Intervention	No. of Participants	In-Person Visits	Web-Based Recruitment	Web-Based Enrollment	Web-Based Consent	Web-Based Outcome Measures	Results Consistent With Traditional Trials
McAlindon,[68] 2003	Randomized, double-blind, placebo-controlled trial	Glucosamine for osteoarthritis of the knee	205	No	Partial, plus magazine advertisements	Partial, plus review of medical records and radiograms	No	Yes	Yes
Ellenberg et al,[69] 2004	Randomized, double-blind, placebo-controlled trial	Tadalafil for erectile dysfunction	83	Yes	No	No	Yes	Yes	Yes
Jacobs et al,[70] 2005	Randomized, double-blind, placebo-controlled trial	Kava for anxiety and valerian for insomnia	391	No	Yes	Yes	Yes	Yes	Partial; previous results were mixed
Wicks et al,[71] 2011	Open-label, matched-control, observational study	Lithium for amyotrophic lateral sclerosis	149 Plus 447 matched controls	No	Yes	Yes	NA	Yes	Yes
Orri et al,[72] 2014	Randomized, single-blind, placebo-controlled trial	Tolterodine tartrate extended release formulation for overactive bladder	18	No	Yes	Yes	Yes	Yes	Yes

Source: JAMA Neurol. 2015 May;72(5):582-8.

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…Or just the primary outcome

Pimavanserin for patients with Parkinson's disease psychosis: a randomised, placebo-controlled phase 3 trial

Jeffrey Cummings, Stuart Isaacson, Roger Mills, Hilde Williams, Kathy Chi-Burris, Anne Corbett, Rohit Dhall, Clive Ballard

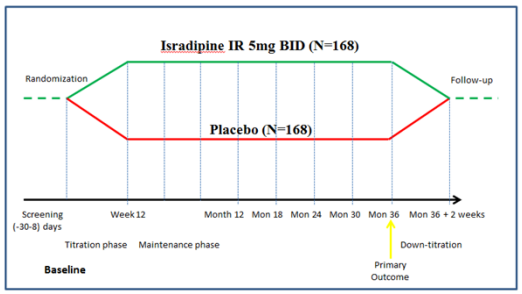
"The SAPS-PD (scale for assessment of positive symptoms-PD adapted) assessments were done by live video conference between the participants and a centralised, independent rater who was masked to treatment assignment."

Lancet. 2014;383:5333-40

We are conducting a Phase III trial of isradipine in early PD at 54 sites in North America: STEADY-PD III

A Phase III, randomized, double-blind, 2-arm parallel group trial with subjects randomized 1:1 to 5mg of Isradipine IR or matching placebo twice daily for 36 months in 336 individuals with early PD

Figure 1. Phase III Study Design



After titration (BL to 12 weeks) visits occur every 3 months in year 1 then every 6 months in years 2 and 3

PSG PARKINSON STUDY GROUP

NINDS U01NS080840 (Biglan) and U01NS080818 (Simuni)

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Virtual Research Visit Pilot Study—REACT-PD

- Observational study assessing feasibility of conducting virtual research visits in a subset of individuals with early PD participating in an ongoing clinical trial (STEADY-PD III)
- 40 participants in STEADY-PD III who consented to be contacted for future research will be enrolled and followed for up to 12 months
- Virtual Research visits to occur within 4 weeks *after* in-person clinical trial visit
- Virtual research visits will collect the same data as is collected at the corresponding in-person visit and include:

Every Visit	Annual Visit Only
UPDRS I-IV*	MDS UPDRS
Hoen and Yahr	MoCA
Schwab and England ADL	PDQ-39
C-SSRS	
Concomitant medications	
Evaluate need for therapy	
Participant/investigator surveys	

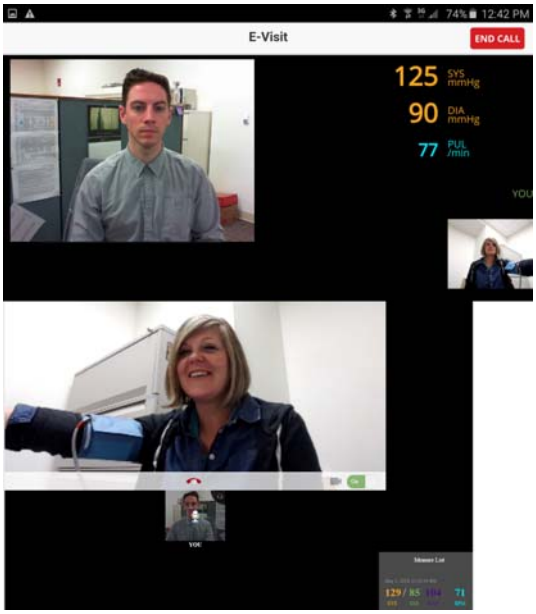
*Primary outcome measure of STEADY-PDIII

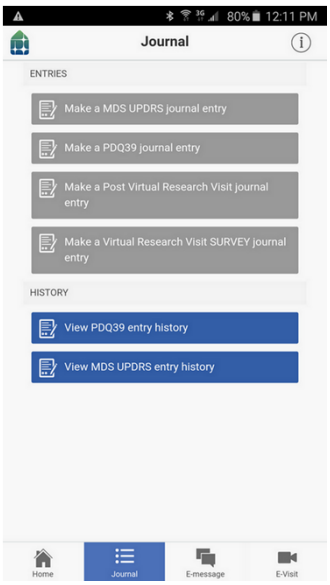
REACT-PD supported by: NIH National Institute of Neurological Disorders and Stroke AMC Health

REACT-PD Aims

1) Feasibility of remote virtual visits
2) Reliability of remote assessments of motor and non-motor function in PD compared with in-person visits
3) Value of remote research visits as measured by willingness to participate in future clinical trial visits remotely

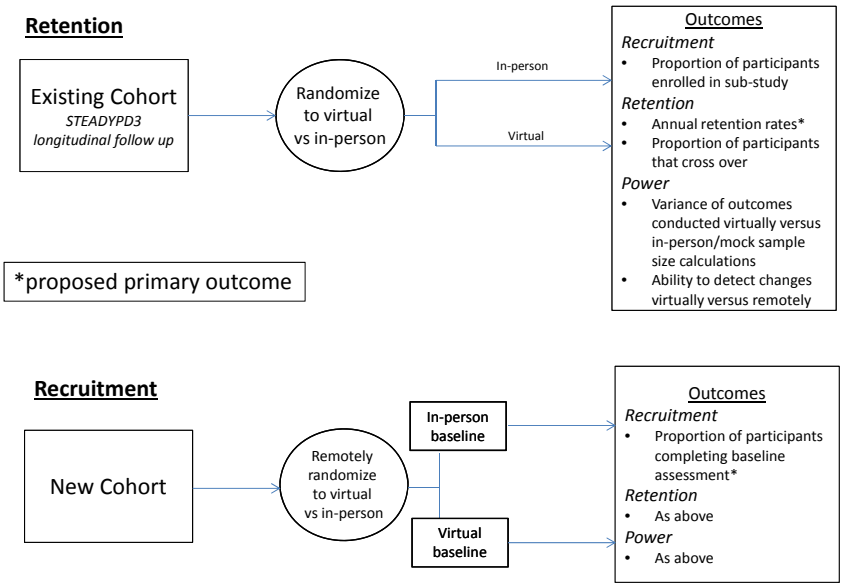
AMC Health Virtual Research Visit





Future directions:

Studying the value of virtual research visits



Summary

- Access to neurological care is vital but limited
- Telemedicine can improve access and outcomes in chronic neurological disorders
- Technology may be a feasible means for improving clinical trial efficiency